K01543

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SECTION 5
SUMMARY OF SAFETY AND EFFECTIVENESS

Submitter's Identification:

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DATE: 28th March 2001 Page (1) of (1)

TO: **FDA ODE**

From: Bernard Tremaine

Subject: **CONTACT INFORMATION**

Dear Sir / Madam,

This page contains all contact information, including E-mail and Web Site addresses.

Best regards,

Bernard J. Tremaine
Consultant in 93/42/EEC general Strategies
IRCA registered Lead Auditor (A007435)
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SECTION 5
SUMMARY OF SAFETY AND EFFECTIVENESS

Date Summary Prepared:	28th March 2001
Name of Device:	
Proprietary name:	TensCare XL-Y3
Common name:	**For the TENS function** - TENS device **For the PMS/EMS function** – Powered Muscle Stimulator
Classification name:	**For TENS functions** Stimulator, Nerve, Transcutaneous, for Pain Relief - **84GZJ; 21 CFR 882.5890**. **For EMS functions** Powered Muscle Stimulator for re-education of muscles - **IPF; 21 CFR 890.5850**
Device Classification:	**For both TENS & EMS functions** - Class II
Predicate Device:	**For the TENS function** TensCare XL-Y2 – (K003591) **For the EMS function** FUJI Dynamics EMS/400 (K913272)
Device Description:	**For the TENS function** A portable TENS device for pain relief. **For the EMS function** A portable EMS device for the re-education of muscles.
Intended Purpose/Use:	**For the TENS function** TENS is used for the relief and management of symptomatic intractable pain and/or as an

	adjunctive treatment in the management of post-surgical and post traumatic acute pain. **For the EMS function** The XL-Y3 is used for the re-education of muscles.
Technological Comparison:	The TensCare XL-Y3 has basic technological characteristics that are substantially equivalent to the TENS and the EMS (Powered Muscle Stimulator) predicate devices. The differences in technological characteristics are the use of a Microprocessor for the control of all functions, the use of pre-set output energy levels selectable by depression of a Button (as opposed to rotational control knobs on the predicate devices) and the use of 'shrouded patient cable connectors' to comply with FDA's Final Rule "Medical Devices: Establishment of Performance Standards for Electrode Lead Wires and Patient Cables".
Labelling Comparison:	The Labelling is substantially equivalent to that of the predicate device.
Non-Clinical Testing:	The results of Bench Testing demonstrate that the output characteristics of the TensCare XL-Y3 are substantially equivalent to those of the two predicate devices.
Clinical Testing:	Clinical Testing was not necessary as no new or innovative aspects have been introduced.
Safety of the Combination functions:	The TensCare XL-Y3 combines the functions of a TENS device and an EMS (Electrical Muscle Stimulator) or Powered Muscle Stimulator, into one package. Bench Testing, VVT and Risk Analysis, including FMEA, demonstrate that

the device performs as intended, with no harm to the User. Also, it is not possible to use the TENS and the EMS functions simultaneously. Mechanical integrity ensures that only one function can be selected at any one time.

Further safety information: The "TensCare XL-Y3" device has been on the European Market for the past two years. During this time a review of Customer Complaints, Returned Product and the results of Post Market Feedback, has demonstrated that the product has performed as Intended, to it's Specified Requirements. The data analysed is summarised in this submission and the full data is available upon request. The Certificate of authority to CE Mark the "TensCare XL-Y3" in accordance with the Medical Device Directive 93/42/EEC is included in Section 12 of this submission.

Conclusions: The TensCare XL-Y3 is substantially equivalent to the predicate devices and any differences between the devices do not pose any new questions of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 31 2001

Bernard J. Tremaine
Medical Device & QA Consultancy
Representing TensCare Ltd.
76, Stockport Road
Timperley, Cheshire
WA15 7SN United Kingdom

Re: 510(k) Number K011543
Trade/Device Name: TensCare, Model XL-Y3
Regulation Numbers: 21 CFR 882.5890 and 21 CFR 890.5850
Regulatory Class: II
Product Codes: GZJ and IPF
Dated: August 19, 2001
Received: August 21, 2001

Dear Mr. Tremaine:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

for Mark N. Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative,
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K011543

SECTION 2
GENERAL INFORMATION

INTENDED USE / PURPOSE STATEMENT

The TensCare "XL-Y3" device combines the functions of both a TENS device and a Muscle Stimulator device.

For the TENS functions, the Intended Purpose is;

"For the symptomatic relief of chronic intractable pain"

For the Muscle Stimulator functions, the Intended Purpose is;

"For the re-education of Muscles"

for Mark N Melkerson
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K011543